## § 17.501

those quality assurance documents which are confidential under the provisions of 38 U.S.C. 5705.

- (c) For purposes of the regulations in §§17.500 through 17.511, the VA's medical quality assurance program consists of systematic healthcare reviews carried out by or for VA for the purpose of improving the quality of medical care or improving the utilization of healthcare resources in VA medical facilities. These review activities may involve continuous or periodic data collection and may relate to either the structure, process, or outcome of health care provided in the VA.
- (d) Nothing in the regulations in §§17.500 through 17.511 shall be construed as authority to withhold any record or document from a committee or subcommittee of either House of Congress or any joint committee or subcommittee of Congress, if such record or document pertains to any matter within the jurisdiction of such committee or joint committee.
- (e) The regulations in §§17.500 through 17.511 do not waive the sovereign immunity of the United States, and do not waive the confidentiality provisions and disclosure restrictions of 38 U.S.C. 5705.

(Authority: 38 U.S.C. 5705)

# § 17.501 Confidential and privileged documents.

- (a) Documents and parts of documents are considered confidential and privileged if they were produced by or for the VA in the process of conducting systematic healthcare reviews for the purpose of improving the quality of health care or improving the utilization of healthcare resources in VA healthcare facilities and meet the criteria in paragraphs (b) and (c) of this section. The four classes of healthcare quality assurance reviews with examples are:
- (1) Monitoring and evaluation reviews conducted by a facility:
  - (i) Medical records reviews,
  - (ii) Drug usage evaluations,
  - (iii) Blood usage reviews,
- (iv) Surgical case/invasive procedure reviews.
- (v) Service and program monitoring including monitoring performed by individual services or programs, several

services or programs working together, or individuals from several services or programs working together as a team,

- (vi) Mortality and morbidity reviews,(vii) Infection control review and surveillance,
- (viii) Occurrence screening,
- (ix) Tort claims peer reviews (except reviews performed to satisfy the requirements of a governmental body or a professional health care organization which is licensing practitioners or monitoring their professional performance).
- (x) Admission and continued stay reviews.
- (xi) Diagnostic studies utilization reviews.
- (xii) Reports of special incidents (VA Form 10-2633 or similar forms) and follow-up documents unless developed during or as a result of a Board of Investigation;
- (2) Focused reviews which address specific issues or incidents and which are designated by the reviewing office at the outset of the review as protected by 38 U.S.C. 5705 and the regulations in §§ 17.500 through 17.511; focused reviews may be either:
  - (i) Facility focused reviews;
- (ii) VA Central Office or Regional focused reviews;
- (3) VA Central Office or Regional general oversight reviews to assess facility compliance with VA program requirements if the reviews are designated by the reviewing office at the outset of the review as protected by 38 U.S.C. 5705 and the regulations in §§ 17.500 through 17.511; and
- (4) Contracted external reviews of care, specifically designated in the contract or agreement as reviews protected by 38 U.S.C. 5705 and the regulations in §§17.500 through 17.511.
- (b) The Under Secretary for Health, Regional Director or facility Director will describe in advance in writing those quality assurance activities included under the classes of healthcare quality assurance reviews listed in paragraph (a) of this section. Only documents and parts of documents resulting from those activities which have been so described are protected by 38 U.S.C. 5705 and the regulations in §§17.500 through 17.511. If an activity is not described in a VA Central Office or

Regional policy document, this requirement may be satisfied at the facility level by description in advance of the activity and its designation as protected in the facility quality assurance plan or other policy document.

- (c) Documents and parts of documents generated by activities which meet the criteria in paragraphs (a) and (b) of this section shall be confidential and privileged only if they:
- (1) Identify, either implicitly or explicitly, individual practitioners, patients, or reviewers except as provided in paragraph (g)(6) of this section; or
- (2) Contain discussions relating to the quality of VA medical care or utilization of VA medical resources by healthcare evaluators during the course of a review of quality assurance information or data, even if they do not identify practitioners, patients, or reviewers; or
- (3) Are individual committee, service, or study team minutes, notes, reports, memoranda, or other documents either produced by healthcare evaluators in deliberating on the findings of healthcare reviews, or prepared for purposes of discussion or consideration by healthcare evaluators during a quality assurance review; or
- (4) Are memoranda, letters, or other documents from the medical facility to the Regional Director or VA Central Office which contain information generated by a quality assurance activity meeting the criteria in §17.501 (a) and (b); or
- (5) Are memoranda, letters, or other documents produced by the Regional Director or VA Central Office which either respond to or contain information generated by a quality assurance activity meeting the criteria in §17.501 (a) and (b).
- (d) Documents which meet the criteria in this section are confidential and privileged whether they are produced at the medical facility, Regional or VA Central Office levels, or by external contractors performing healthcare quality assurance reviews.
- (e) Documents which are confidential and privileged may be in written, computer, electronic, photographic or any other form.
- (f) Documents which contain confidential and privileged material in one

part, but not in others, such as Clinical Executive Board minutes, should be filed and maintained as if the entire document was protected by 38 U.S.C. 5705. This is not required if the confidential and privileged material is deleted.

- (g) The following records and documents and parts of records and documents are not confidential even if they meet the criteria in paragraphs (a) through (c) of this section:
- (1) Statistical information regarding VA healthcare programs or activities that does not implicitly or explicitly identify individual VA patients or VA employees or individuals involved in the quality assurance process;
- (2) Summary documents or records which only identify study topics, the period of time covered by the study, criteria, norms, and/or major overall findings, but which do not identify individual healthcare practitioners, even by implication;
- (3) The contents of Credentialing and Privileging folders as described in VACO policy documents (38 U.S.C. 5705-protected records shall not be filed in Credentialing and Privileging folders);
- (4) Records and documents developed during or as a result of Boards of Investigations;
- (5) Completed patient satisfaction survey questionnaires and findings from patient satisfaction surveys;
- (6) Records and documents which only indicate the number of patients treated by a practitioner, either by diagnosis or in aggregate, or number of procedures performed by a practitioner, either by procedure or in aggregate;
- (7) Records and documents developed during or as a result of reviews performed to satisfy the requirements of a governmental body or a professional healthcare organization which is licensing practitioners or monitoring their professional performance, e.g., National Practitioner Data Bank, Federation of State Medical Boards, and National Council of State Boards of Nursing:
- (8) Documents and reports developed during or as a result of site visits by the Office of the Medical Inspector except to the extent that the documents and reports contain information that

## § 17.502

meets the criteria described in this section and are produced by or for VA by other than the Office of Medical Inspector:

- (9) External reviews conducted by VA Central Office or a Region other than those designated by the reviewing office under paragraph (a)(2) or (a)(3) of this section as protected by 38 U.S.C. 5705 and the regulations in §§17.500 through 17.511;
- (10) Documents and reports of Professional Standards Boards, Credentialing Committees, Executive Committees of Medical Staff, and similar bodies, insofar as the documents relate to the credentialing and privileging of practitioners:
- (11) Documents and reports developed during or as a result of data validation activities:
- (12) Documents and reports developed during or as a result of occupational health monitoring;
- (13) Documents and reports developed during or as a result of safety monitoring not directly related to the care of specified individual patients;
- (14) Documents and reports developed during or as a result of resource management activities not directly related to the care of specified individual patients; and
- (15) Information and records derived from patient medical records or facility administrative records, which are not protected by 38 U.S.C. 5705 and the regulations in §§ 17.500 through 17.511, may be sent or communicated to a third party payor who has asked for this information in response to a VA request for reimbursement based on Public Law 99-272 and Public Law 101-508. Reviews conducted at the request of the third party payor do not generate records protected by 38 U.S.C. 5705 and the regulations in §§ 17.500 through 17.511 since the reviews are not undertaken as part of the VA's quality assurance program.

(Authority: 38 U.S.C. 5705)

## § 17.502 Applicability of other statutes.

(a) Disclosure of quality assurance records and documents which are not confidential and privileged under 38 U.S.C. 5705 and the confidentiality regulations in §§17.500 through 17.511 will be governed by the provisions of the

Freedom of Information Act, and, if applicable, the Privacy Act and any other VA or federal confidentiality statutes.

(b) When included in a quality assurance review, confidential records protected by other confidentiality statutes such as 5 U.S.C. 552a (the Privacy Act), 38 U.S.C. 7332 (drug and alcohol abuse, sickle cell anemia, HIV infection), and 38 U.S.C. 5701 (veterans' names and addresses) retain whatever confidentiality protection they have under these laws and applicable regulations and will be handled accordingly. To the extent that information protected by 38 U.S.C. 5701 or 7332 or the Privacy Act is incorporated into quality assurance records, the information in the quality assurance records is still protected by these statutes.

(Authority: 38 U.S.C. 5705)

#### §17.503 Improper disclosure.

- (a) Improper disclosure is the disclosure of confidential and privileged healthcare quality assurance review records or documents (or information contained therein), as defined in §17.501, to any person who is not authorized access to the records or documents under the statute and the regulations in §\$17.500 through 17.511.
- (b) "Disclosure" means the communication, transmission, or conveyance in any way of any confidential and privileged quality assurance records or documents or information contained in them to any individual or organization in any form by any means.

(Authority: 38 U.S.C. 5705)

### § 17.504 Disclosure methods.

(a) Disclosure of confidential and privileged quality assurance records and documents or the information contained therein outside VA, where permitted by the statute and the regulations in §§17.500 through 17.511, will always be by copies, abstracts, summaries, or similar records or documents prepared by the Department of Veterans Affairs and released to the requestor. The original confidential and privileged quality assurance records and documents will not be removed from the VA facility by any person, VA